



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/528,288

04/13/2005

Richard A. Joseph

NEN-21902/16

4906

37742 7590 05/16/2007
GIFFORD, KRASS, SPRINKLE, ANDERSON
& CITKOWSKI, P.C.
P.O. BOX 7021
TROY, MI 48007-7021

EXAMINER

SISSON, BRADLEY L

ART UNIT

PAPER NUMBER

1634

MAIL DATE

DELIVERY MODE

05/16/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/528,288	Applicant(s) JOSEPH ET AL.	
	Examiner Bradley L. Sisson	Art Unit 1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-12,15-19,21-28 and 39 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1,3-12,15-19,21-28 and 39 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>3/17/05 & 4/13/05</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

2. The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

3. Claims 1, 3, 7-9, 11, 12, 15-19, 21, 24-26, and 28 are rejected under 35 U.S.C. 102(e) as being anticipated by US Patent 7,056,676 B2 (Korlach et al.).

4. Korlach et al., discloses and claims a method of sequencing of sequencing nucleic acid via primer extension reactions wherein a labeled nucleotide is incorporated into a nascent strand. For purposes of examination, the “primer” of Korlach et al., is considered to meet the limitation of applicant’s “oligonucleotide.”

5. As seen at columns 11-12, any of a variety of fluorescent moieties, including metals, can be used in conjunction with the disclosed method of detecting oligonucleotide elongation.

Art Unit: 1634

6. Kurlach et al., column 1, bridging to column 2, disclose performing polymerase chain reaction (PCR). This meets a limitation of claim 7.
7. Kurlach et al., column 26, discloses performing fluorescence resonance energy transfer (FRET). This meets a limitation of claim 12.
8. Kurlach et al., teaches serial detection of nucleotides that are incorporated into the growing strand. The aspect of having a first and second measurement speaks to measuring fluorescence parameters of the elongation reaction at first and second time points. This meets a limitation of claims 15-19 and 21-28.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

11. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various

Art Unit: 1634

claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

12. Claims 4, 6, 10, 23, 27, and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent 7,056,676 B2 (Korlach et al.) in view of US Patent 5,824,481 (Kambara et al.).

13. See above for the basis of the rejection as it relates to Korlach et al.

14. Korlach et al., while disclosing the use of virtually any type of fluorescent compound, does not identify fluorescent compounds that comprise a metal, nor the use of ligase.

15. Kambara et al., disclose a variety of sequencing reactions (applicant's oligonucleotide elongation reaction) wherein a detectably-labeled nucleotide is incorporated.

16. Kambara et al., column 6, teach using ligase in conjunction with the fluorescent metal ruthenium.

17. The above showing is deemed to meet a limitation of claims 4, 6, 10, 23, 27, and 39.

18. It would have been obvious to one of ordinary skill in the art to substitute alternative labels and enzymes in the method of Korlach et al., as disclosed by Kambara et al., as such would have offered further design and operational choices, thereby allowing for the detection and analysis of nucleic acids of interest from more perspectives.

19. Claims 5 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent 7,056,676 B2 (Korlach et al.) in view of US Patent 6,444,111 B1 (Montgomery).

Art Unit: 1634

See above for the basis of the rejection as it relates to the disclosure of Korlach et al.

Korlach et al., has not been found to disclose the use of fluorescence in conjunction with platinum.

Montgomery discloses performing a variety of oligonucleotide elongation reactions wherein fluorescence is generated and platinum is used as a quencher of unwanted, unintentional fluorescence.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the method of Korlach et al., so to incorporate the presence of platinum of Montgomery as such would have allowed the artisan to readily quench any unwanted fluorescence, thereby increasing the sensitivity and accuracy of the assay.

In view of the detailed teachings of the prior art of record, the ordinary artisan would have had a most reasonable expectation of success.

Conclusion

20. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bradley L. Sisson whose telephone number is (571) 272-0751.

The examiner can normally be reached on 6:30 a.m. to 5 p.m., Monday through Thursday.

21. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1634

22. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Bradley L. Sisson
Primary Examiner
Art Unit 1634

BLS